

**Impact of Prescription  
Drug User Fee Program  
- Human Drugs -**

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**Overall Assessment**

**Program has been successful in  
achieving its original goals:**

- Eliminate backlogs
- Decrease review times
- Shorten time to approval

**PDUFA Benefits: Public**

- Faster access to new therapies
- Increased industry incentive to  
invest in new therapeutic areas
- Greater openness of the process
- Improved drug development

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### **PDUFA Benefits: FDA Drug Regulation**

- **Improved resources**
  - More reviewers, pre-approval inspectors, computer staff
  - Upgraded infrastructure
  - Highly-skilled new staff
- **Better industry applications**
- **Streamlined processes**

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### **PDUFA Benefits: Pharmaceutical Industry**

- **Predictable process**
- **Faster process**
- **Greater openness**
- **Access to Agency advice & input**

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### **Challenges of PDUFA**

- **Covers limited part of drug life cycle - premarket review - does not support:**
  - Drug safety surveillance after approval
  - Drug advertising regulation
  - GMP surveillance
- **Limits FDA flexibility to manage resources**
- **Tracking subsidiary goals is burdensome**

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